

Docket: 10/748,117

In the claims:

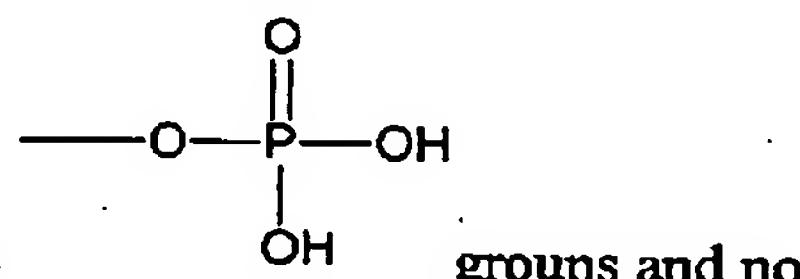
1. (Original) An immunogenic composition comprising: (a) water; (b) a polymer microparticle comprising a polymer selected from a poly(α -hydroxy acid), a polyhydroxy butyric acid, a polycaprolactone, a polyorthoester, a polyanhydride, and a polycyanoacrylate; (c) an antigen adsorbed to the microparticle; and (d) a synthetic phospholipid compound comprising: (i) one or more phosphoryl groups independently



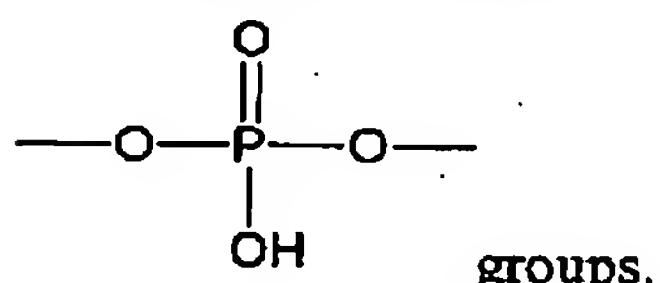
selected from a group and a group; (ii) a plurality of

linear alkane groups, $\left[CH_2\right]_nCH_3$, in which n is independently an integer ranging from 6 to 20.

2. (Original) The immunogenic composition of claim 1, wherein the phospholipid

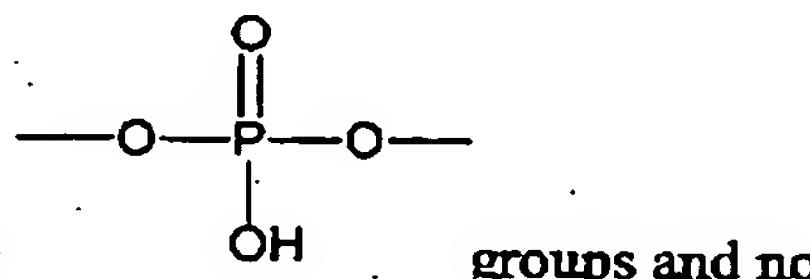


compound comprises one or more groups and no

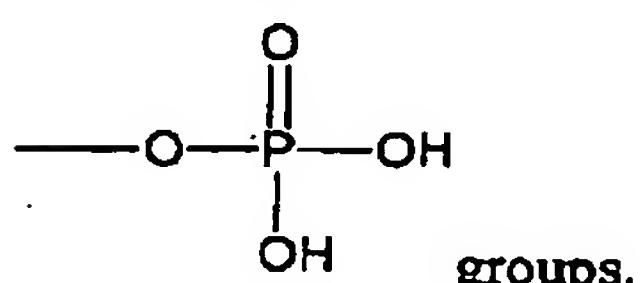


groups.

3. (Original) The immunogenic composition of claim 1, wherein the phospholipid



compound comprises one or more groups and no



groups.

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4. (Original) The immunogenic composition of claim 1, wherein the phospholipid

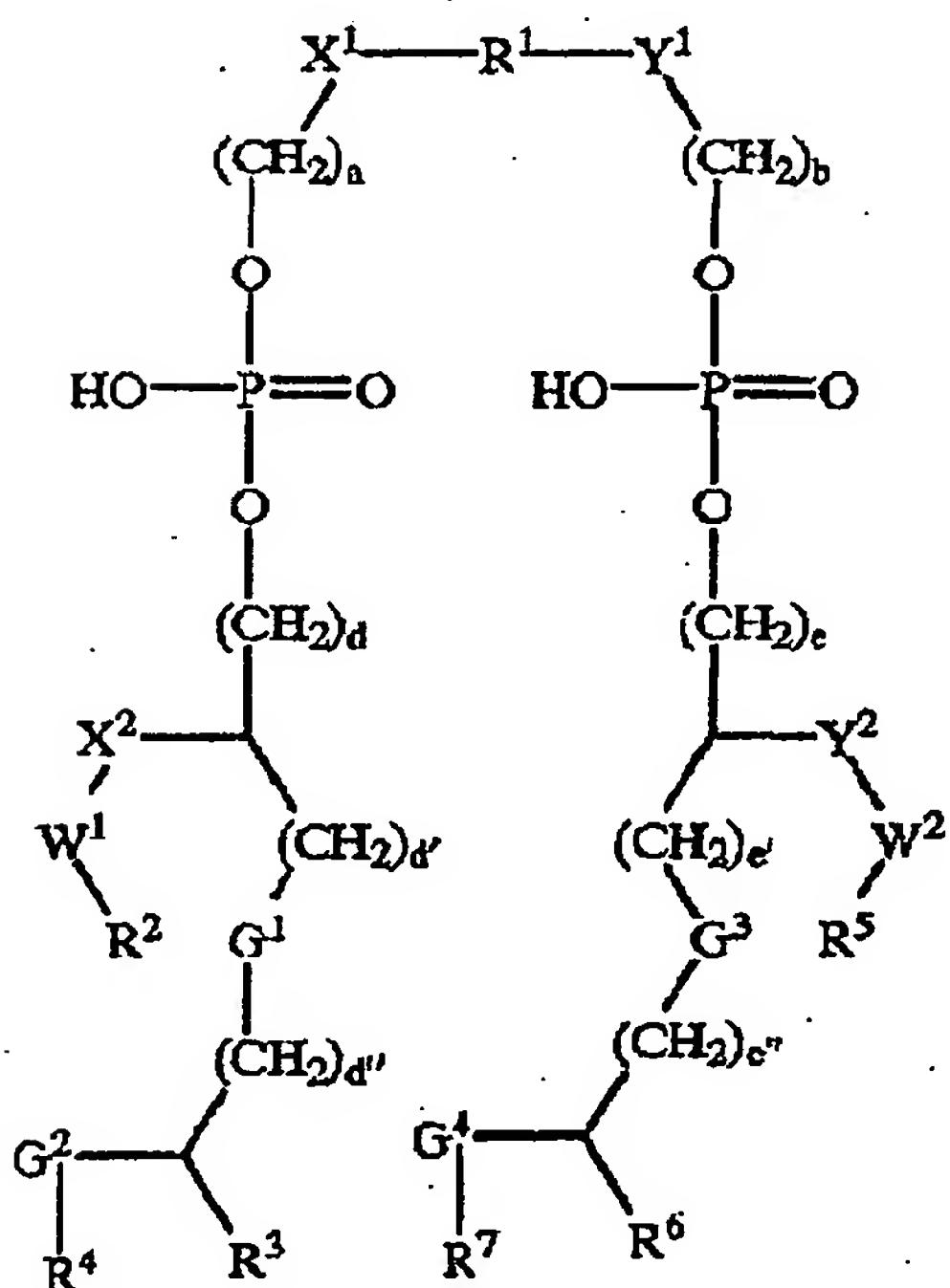
compound comprises four to eight of said $-\left[\text{CH}_2\right]_n\text{CH}_3$ groups.

5. (Original) The immunogenic composition of claim 1, wherein the phospholipid

compound comprises six of said $-\left[\text{CH}_2\right]_n\text{CH}_3$ groups.

6. (Original) The immunogenic composition of claim 1, wherein the phospholipid compound does not comprise a saccharide group.

7. (Original) The immunogenic composition of claim 1, wherein the phospholipid compound is a compound having the following formula:



wherein:

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R^1 is selected from the group consisting of

- (a) $C(O)$;
- (b) $C(O)-C_{1-14}$ alkyl- $C(O)$, wherein the C_{1-14} alkyl is optionally substituted with hydroxy, C_{1-5} alkoxy, C_{1-5} alkyleneoxy, C_{1-5} alkylamino, or C_{1-5} -alkyl-aryl, wherein the aryl moiety of the C_{1-5} -alkyl-aryl is optionally substituted with C_{1-5} alkoxy, C_{1-5} alkylamino, C_{1-5} alkoxy-amino, C_{1-5} alkylamino- C_{1-5} alkoxy, $-O-C_{1-5}$ alkylamino- C_{1-5} alkoxy, $-O-C_{1-5}$ alkylamino- $C(O)-C_{1-5}$ alkyl $C(O)OH$, $-O-C_{1-5}$ alkylamino- $C(O)-C_{1-5}$ alkyl- $C(O)-C_{1-5}$ alkyl;
- (c) C_2 to C_{15} straight or branched chain alkyl optionally substituted with hydroxy or alkoxy; and
- (d) $-C(O)-C_{6-12}$ arylene- $C(O)-$ wherein the arylene is optionally substituted with hydroxy, halogen, nitro or amino;

a and b are independently 0, 1, 2, 3 or 4;

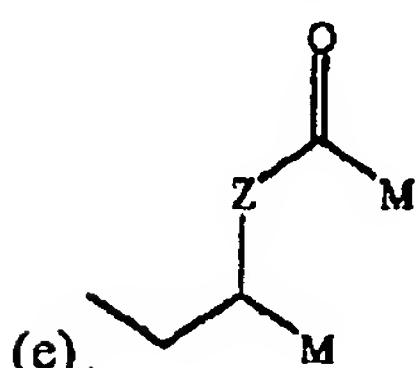
d , d' , d'' , e , e' and e'' are independently an integer from 1 to 4;

X^1 , X^2 , Y^1 and Y^2 are independently selected from the group consisting of a null, oxygen, NH and $N(C(O)C_{1-4}$ alkyl), and $N(C_{1-4}$ alkyl) $_2$;

W^1 and W^2 are independently selected from the group consisting of carbonyl, methylene, sulfone and sulfoxide;

R^2 and R^5 are independently selected from the group consisting of:

- (a) C_2 to C_{20} straight chain or branched chain alkyl which is optionally substituted with oxo, hydroxy or alkoxy;
- (b) C_2 to C_{20} straight chain or branched chain alkenyl or dialkenyl which is optionally substituted with oxo, hydroxy or alkoxy;
- (c) C_2 to C_{20} straight chain or branched chain alkoxy which is optionally substituted with oxo, hydroxy or alkoxy;
- (d) $-NH-C_2$ to C_{20} straight chain or branched chain alkyl, wherein the alkyl group is optionally substituted with oxo, hydroxy or alkoxy; and



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wherein Z is selected from the group consisting of O and NH, and M and N are independently selected from the group consisting of C₂ to C₂₀ straight chain or branched chain alkyl, alkenyl, alkoxy, acyloxy, alkylamino, and acylamino; R³ and R⁶ are independently selected from the group consisting of C₂ to C₂₀ straight chain or branched chain alkyl or alkenyl, optionally substituted with fluoro or oxo; R⁴ and R⁷ are independently selected from the group consisting of C(O)C₂ to C₂₀ straight chain or branched chain alkyl or alkenyl; C₂ to C₂₀ straight chain or branched chain alkyl; C₂ to C₂₀ straight chain or branched chain alkoxy; C₂ to C₂₀ straight chain or branched chain alkenyl; wherein the alkyl, alkenyl or alkoxy groups are independently and optionally substituted with hydroxy, fluoro or C₁ to C₅ alkoxy; G¹, G², G³ and G⁴ are independently selected from the group consisting of oxygen, methylene, amino, thiol, —NHC(O)—, and —N(C(O)C₁₋₄ alkyl)—; or G² R⁴ or G⁴ R⁷ may together be a hydrogen atom or hydroxyl; or a pharmaceutically acceptable salt thereof.

8. (Original) The immunogenic composition of claim 7, wherein R¹ is C(O); a, b, d, d', d'', e, e' and e'' are independently 1 or 2; X¹, X², Y¹ and Y² are NH; W¹ and W² are carbonyl; R² and R⁵ are C₁₀ to C₂₀ straight chain alkyl which is substituted with oxo; R³ and R⁶ are C₅-C₁₀ straight chain alkyl; R⁴ and R⁷ are C(O)C₈-C₁₄ straight chain alkyl or alkenyl; and G¹, G², G³ and G⁴ are oxygen.

9. (Original) The immunogenic composition of claim 7, wherein R¹ is C(O); a and b are 2; d, d', e and e' are 1; d'' and e'' are 2; X¹, X², Y¹ and Y² are NH; W¹ and W² are carbonyl; R² and R⁵ are C₁₃ straight chain alkyl which is substituted with oxo at the 2 position; R³ and R⁶ are C₇ straight chain alkyl; R⁴ and R⁷ are C(O)C₁₁ straight chain alkyl; G¹, G², G³ and G⁴ are oxygen.

10. (Currently amended) The immunogenic composition of ~~any of claims 1-9~~ claim 1, wherein the phospholipid is entrapped within the microparticles.

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11. (Currently amended) The immunogenic composition of ~~any of claims 1-9 claim~~
1, wherein the phospholipid is adsorbed to the microparticles.

12. (Currently amended) The immunogenic composition of ~~any of claims 1-9 claim~~
1, wherein the phospholipid is dispersed in aqueous solution.

13. (Currently amended) The immunogenic composition of ~~any of claims 1-9 claim~~
1, wherein two or more antigens are adsorbed to the microparticles.

14. (Currently amended) The immunogenic composition of ~~any of claims 1-9 claim~~
1, wherein additional antigen is entrapped within the microparticles.

15. (Currently amended) The immunogenic composition of ~~any of claims 1-9 claim~~
1, wherein the antigen is a polypeptide-containing antigen.

16. (Currently amended) The immunogenic composition of ~~any of claims 1-9 claim~~
1, wherein the antigen is a polynucleotide-containing antigen.

17. (Currently amended) The immunogenic composition of ~~any of claims 1-9 claim~~
1, wherein the antigen is derived from a tumor cell.

18. (Currently amended) The immunogenic composition of ~~any of claims 1-9 claim~~
1, wherein the antigen is derived from a pathogenic organism.

19. (Original) The immunogenic composition of claim 18, wherein the pathogenic organism is selected from a virus, a bacterium, a fungus and a parasite.

20. (Original) The immunogenic composition of claim 18, wherein the pathogenic organism is selected from HIV, hepatitis B virus, hepatitis C virus, meningitis B, *Haemophilus influenza* type B, pertussis, diphtheria, tetanus, and influenza A virus.

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21. (Original) The immunogenic composition of claim 18, wherein the pathogenic organism is selected from human immunodeficiency virus, *Neisseria meningitidis*, and hepatitis virus.

22. (Currently amended) The immunogenic composition of ~~any of claims 1-9 claim~~ 1, wherein the immunogenic composition further comprises a surfactant.

23. (Currently amended) The immunogenic composition of ~~any of claims 1-9 claim~~ 1, wherein the microparticles have a diameter between 500 nanometers and 20 microns.

24. (Currently amended) The immunogenic composition of ~~any of claims 1-9 Claim~~ 1, wherein the poly(α -hydroxy acid) is selected from poly(L-lactide), poly(D,L-lactide) and poly(lactide-co-glycolide).

25. (Currently amended) The immunogenic composition of ~~any of claims 1-9 claim~~ 1, wherein the poly(α -hydroxy acid) is poly(D,L-lactide-co-glycolide).

26. (Original) The immunogenic composition of claim 25, wherein the poly(D,L-lactide-co-glycolide) has a lactide:glycolide molar ratio ranging from 40:60 to 60:40.

27. (Currently amended) The immunogenic composition of ~~any of claims 1-9 claim~~ 1, further comprising a supplemental immunological adjuvant.

28. (Currently amended) The immunogenic composition of ~~any of claims 1-9 claim~~ 1, wherein the immunogenic composition is an injectable composition.

29. (Currently amended) A method of delivering a therapeutic amount of an antigen to a vertebrate host animal, comprising administering to the host animal the immunogenic composition of ~~any of claims 1-9 claim~~ 1.

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30. (Currently amended) A method of treating a host animal having a pathogenic organism infection or tumor comprising administering to the animal the immunogenic composition of ~~any of claims 1-9~~ claim 1.

31. (Currently amended) A method of immunizing a host animal against a tumor or infection by a pathogenic organism comprising administering to the animal the immunogenic composition of ~~any of claims 1-9~~ claim 1.

32. (Currently amended) A method of stimulating an immune response in a host animal, comprising administering to the host animal the immunogenic composition of ~~any of claims 1-9~~ claim 1.

33. (Original) The method of claim 32, wherein the immune response comprises a humoral immune response.

34. (Original) The method of claim 32, wherein the immune response comprises a cellular immune response.

35. (Original) The method of claim 32, wherein the immune response is raised against a viral, bacterial, or parasitic infection.

36. (Original) The method of claim 32, wherein the immune response is raised against a tumor.

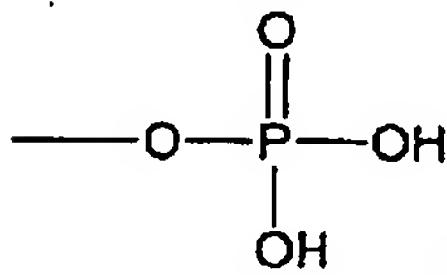
37. (Original) The method of claim 32, wherein the host animal is a vertebrate animal.

38. (Original) The method of claim 32, wherein the host animal is a mammal.

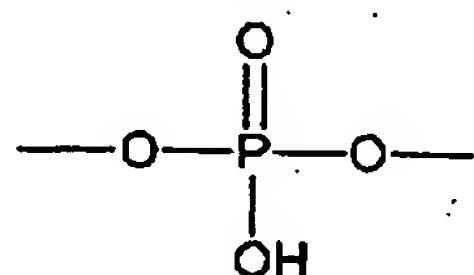
39. (Original) The method of claim 32, wherein the host animal is a human.

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40. (Original) An immunogenic composition comprising: (a) water; (b) a metabolizable oil; (c) an emulsifying agent; (d) an antigen; and (e) a phospholipid compound comprising: (i) one or more phosphoryl groups independently selected from a



group and a

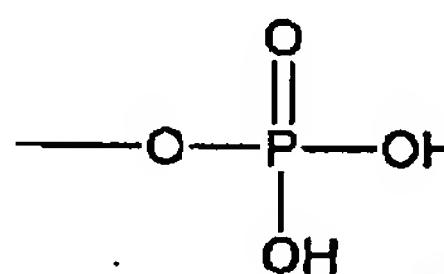


group; (ii) a plurality of linear alkane

groups, $\left[\text{CH}_2 \right]_n \text{CH}_3$, in which n is independently an integer ranging from 6 to 20, wherein the composition is an oil-in-water emulsion having oil and aqueous phases, and

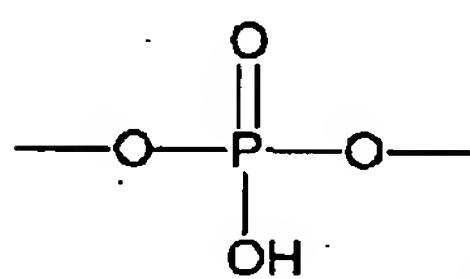
wherein the oil phase is in the form of oil droplets substantially all of which are less than 1 micron in diameter.

41. (Original) The immunogenic composition of claim 40, wherein the



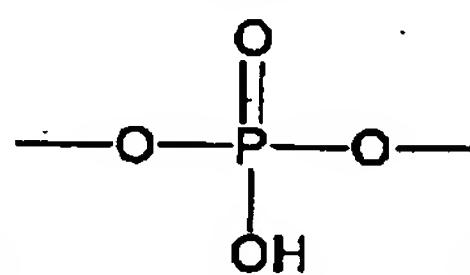
phospholipid compound comprises one or more

groups and no



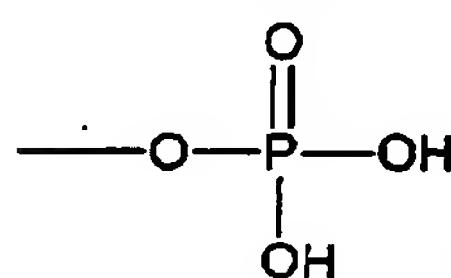
groups.

42. (Original) The immunogenic composition of claim 40, wherein the



phospholipid compound comprises one or more

groups and no



groups.

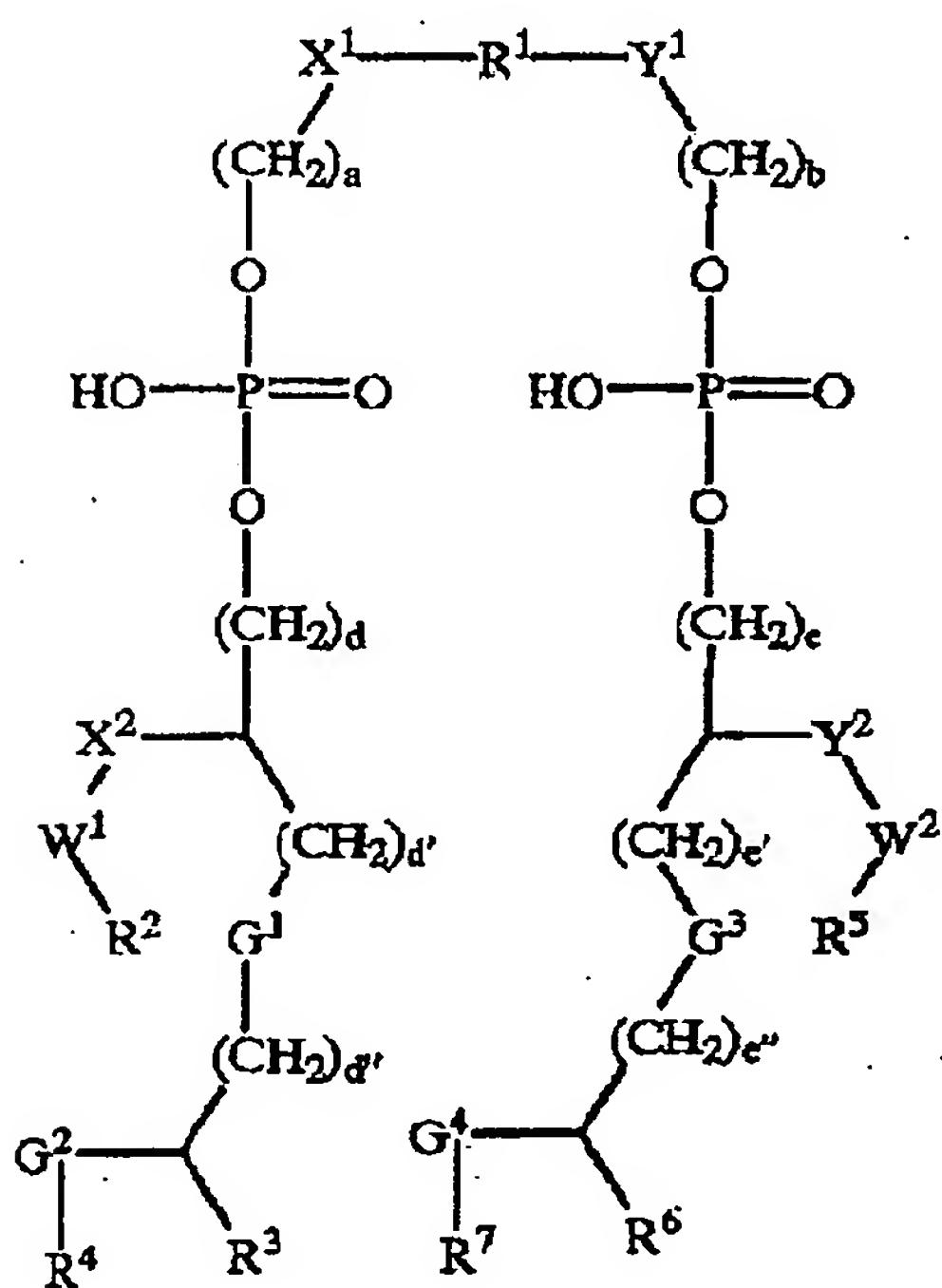
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43. (Original) The immunogenic composition of claim 40, wherein the phospholipid compound comprises four to eight of said $\left[\text{CH}_2\right]_n\text{CH}_3$ groups.

44. (Original) The immunogenic composition of claim 40, wherein the phospholipid compound comprises six of said $\left[\text{CH}_2\right]_n\text{CH}_3$ groups.

45. (Original) The immunogenic composition of claim 40, wherein the phospholipid compound does not comprise a saccharide group.

46. (Original) The immunogenic composition of claim 40, wherein the phospholipid compound is a compound having the following formula:



wherein:

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R^1 is selected from the group consisting of

- (a) $C(O)$;
- (b) $C(O)-C_{1-14}$ alkyl- $C(O)$, wherein the C_{1-14} alkyl is optionally substituted with hydroxy, C_{1-5} alkoxy, C_{1-5} alkylenedioxy, C_{1-5} alkylamino, or C_{1-5} -alkyl-aryl, wherein the aryl moiety of the C_{1-5} -alkyl-aryl is optionally substituted with C_{1-5} alkoxy, C_{1-5} alkylamino, C_{1-5} alkoxy-amino, C_{1-5} alkylamino- C_{1-5} alkoxy, $-O-C_{1-5}$ alkylamino- C_{1-5} alkoxy, $-O-C_{1-5}$ alkylamino- $C(O)-C_{1-5}$ alkyl $C(O)OH$, $-O-C_{1-5}$ alkylamino- $C(O)-C_{1-5}$ alkyl- $C(O)-C_{1-5}$ alkyl;
- (c) C_2 to C_{15} straight or branched chain alkyl optionally substituted with hydroxy or alkoxy; and
- (d) $-C(O)-C_{6-12}$ arylene- $C(O)-$ wherein the arylene is optionally substituted with hydroxy, halogen, nitro or amino;

a and b are independently 0, 1, 2, 3 or 4;

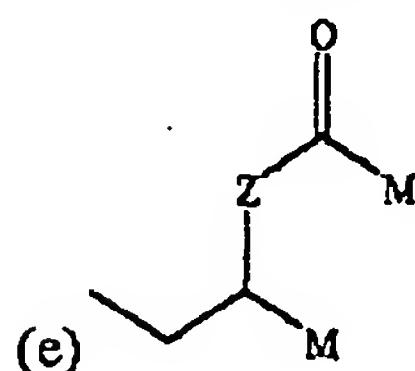
d , d' , d'' , e , e' and e'' are independently an integer from 1 to 4;

X^1 , X^2 , Y^1 and Y^2 are independently selected from the group consisting of a null, oxygen, NH and $N(C(O)C_{1-4}$ alkyl), and $N(C_{1-4}$ alkyl)₂;

W^1 and W^2 are independently selected from the group consisting of carbonyl, methylene, sulfone and sulfoxide;

R^2 and R^5 are independently selected from the group consisting of:

- (a) C_2 to C_{20} straight chain or branched chain alkyl which is optionally substituted with oxo, hydroxy or alkoxy;
- (b) C_2 to C_{20} straight chain or branched chain alkenyl or dialkenyl which is optionally substituted with oxo, hydroxy or alkoxy;
- (c) C_2 to C_{20} straight chain or branched chain alkoxy which is optionally substituted with oxo, hydroxy or alkoxy;
- (d) $-NH-C_2$ to C_{20} straight chain or branched chain alkyl, wherein the alkyl group is optionally substituted with oxo, hydroxy or alkoxy; and



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wherein Z is selected from the group consisting of O and NH, and M and N are independently selected from the group consisting of C₂ to C₂₀ straight chain or branched chain alkyl, alkenyl, alkoxy, acyloxy, alkylamino, and acylamino; R³ and R⁶ are independently selected from the group consisting of C₂ to C₂₀ straight chain or branched chain alkyl or alkenyl, optionally substituted with fluoro or oxo; R⁴ and R⁷ are independently selected from the group consisting of C(O)C₂ to C₂₀ straight chain or branched chain alkyl or alkenyl; C₂ to C₂₀ straight chain or branched chain alkyl; C₂ to C₂₀ straight chain or branched chain alkoxy; C₂ to C₂₀ straight chain or branched chain alkenyl; wherein the alkyl, alkenyl or alkoxy groups are independently and optionally substituted with hydroxy, fluoro or C₁ to C₅ alkoxy; G¹, G², G³ and G⁴ are independently selected from the group consisting of oxygen, methylene, amino, thiol, —NHC(O)—, and —N(C(O)C₁₋₄ alkyl)—; or G² R⁴ or G⁴ R⁷ may together be a hydrogen atom or hydroxyl; or a pharmaceutically acceptable salt thereof. (Original)

47. (Original) The immunogenic composition of claim 46, wherein R¹ is C(O); a, b, d, d', d'', e, e' and e'' are independently 1 or 2; X¹, X², Y¹ and Y² are NH; W¹ and W² are carbonyl; R² and R⁵ are C₁₀ to C₂₀ straight chain alkyl which is substituted with oxo; R³ and R⁶ are C₅-C₁₀ straight chain alkyl; R⁴ and R⁷ are C(O)C₈-C₁₄ straight chain alkyl or alkenyl; and G¹, G², G³ and G⁴ are oxygen.

48. (Original) The immunogenic composition of claim 46, wherein R¹ is C(O); a and b are 2; d, d', e and e' are 1; d'' and e'' are 2; X¹, X², Y¹ and Y² are NH; W¹ and W² are carbonyl; R² and R⁵ are C₁₃ straight chain alkyl which is substituted with oxo at the 2 position; R³ and R⁶ are C₇ straight chain alkyl; R⁴ and R⁷ are C(O)C₁₁ straight chain alkyl; G¹, G², G³ and G⁴ are oxygen.

49. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ ~~claim 40~~, wherein substantially all of the oil droplets are less than 500 nm in diameter.

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50. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ ~~claim 40~~, wherein substantially all of the oil droplets are less than 250 nm in diameter.

51. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ ~~claim 40~~, wherein the metabolizable oil is selected from an animal oil and a vegetable oil.

52. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ ~~claim 40~~, wherein the metabolizable oil is a fish oil.

53. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ ~~claim 40~~, wherein the metabolizable oil is a branched, polyunsaturated hydrocarbon having from 20-40 carbon atoms.

54. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ ~~claim 40~~, wherein the metabolizable oil is a terpenoid.

55. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ ~~claim 40~~, wherein the metabolizable oil is squalene.

56. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ ~~claim 40~~, wherein the emulsifying agent comprises a sorbitan derivative.

57. (Original) The immunogenic composition of claim 56, wherein the sorbitan derivative is selected sorbitan fatty acid monoesters, sorbitan fatty acid sesquiesters, sorbitan fatty acid triesters, polyoxyethylene sorbitan fatty acid monoesters and polyoxyethylene sorbitan fatty acid triesters.

58. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ ~~claim 40~~, wherein the composition comprises a plurality of emulsifying agents.

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59. (Original) The immunogenic composition of claim 58, wherein the composition comprises a sorbitan ester and a polyoxyethylene sorbitan ester.

60. (Original) The immunogenic composition of claim 59, wherein the composition comprises polyoxyethylene sorbitan monooleate and sorbitan trioleate.

61. (Original) The immunogenic composition of claim 58, wherein the composition comprises a first emulsifying agent having an HLB value ranging from 1 to 9 and a second emulsifying agent having an HLB value ranging from 10 to 20.

62. (Original) The immunogenic composition of claim 58, wherein the composition comprises a first emulsifying agent having an HLB value ranging from 1 to 4 and a second emulsifying agent having an HLB value ranging from 12 to 17.

63. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ claim 40, wherein the phospholipid is dissolved or dispersed in the oil phase.

64. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ claim 40, wherein the phospholipid is dispersed in the aqueous phase.

65. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ claim 40, wherein the antigen is dissolved or dispersed in the aqueous phase.

66. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ claim 40, wherein the antigen is a polypeptide-containing antigen.

67. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ claim 40, wherein the antigen is a polynucleotide-containing antigen.

68. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ claim 40, wherein the antigen is derived from a tumor cell.

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69. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ claim 40, wherein the antigen is derived from a pathogenic organism.

70. (Original) The immunogenic composition of claim 69, wherein the pathogenic organism is selected from a virus, a bacterium, a fungus and a parasite.

71. (Original) The immunogenic composition of claim 69, wherein the pathogenic organism is selected from HIV, hepatitis B virus, hepatitis C virus, meningitis B, *Haemophilus influenza* type B, pertussis, diphtheria, tetanus, and influenza A virus.

72. (Original) The immunogenic composition of claim 69, wherein the pathogenic organism is selected from human immunodeficiency virus, *Neisseria meningitidis*, and hepatitis virus.

73. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ claim 40, further comprising a supplemental immunological adjuvant.

74. (Currently amended) The immunogenic composition of ~~any of claims 40-48~~ claim 40, wherein the immunogenic composition is an injectable composition.

75. (Currently amended) A method of delivering a therapeutic amount of an antigen to a vertebrate host animal, comprising administering to the host animal the immunogenic composition of ~~any of claims 40-48~~ claim 40.

76. (Currently amended) A method of treating a host animal having a pathogenic organism infection or tumor comprising administering to the animal the immunogenic composition of ~~any of claims 40-48~~ claim 40.

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77. (Currently amended) A method of immunizing a host animal against a tumor or infection by a pathogenic organism comprising administering to the animal the immunogenic composition of ~~any of claims 40-48~~ claim 40.

78. (Currently amended) A method of stimulating an immune response in a host animal, comprising administering to the host animal the immunogenic composition of ~~any of claims 40-48~~ claim 40.

79. (Original) The method of claim 78, wherein the immune response comprises a humoral immune response.

80. (Original) The method of claim 78, wherein the immune response comprises a cellular immune response.

81. (Original) The method of claim 78, wherein the immune response is raised against a viral, bacterial, or parasitic infection.

82. (Original) The method of claim 78, wherein the immune response is raised against a tumor.

83. (Original) The method of claim 78, wherein the host animal is a vertebrate animal.

84. (Original) The method of claim 78, wherein the host animal is a mammal.

85. (Original) The method of claim 78, wherein the host animal is a human.

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